Agency for Healthcare Research and Quality
Advancing Excellence in Health Care

NATIONAL GUIDELINE CLEARINGHOUSE

General

Guideline Title

Gastrointestinal opportunistic infections. In: British HIV Association and British Infection Association guidelines for the treatment of opportunistic infection in HIV-seropositive individuals 2011.

Bibliographic Source(s)

Beeching NJ, Jones R, Gazzard B. Gastrointestinal opportunistic infections. In: British HIV Association and British Infection Association guidelines for the treatment of opportunistic infection in HIV-seropositive individuals 2011. HIV Med. 2011 Sep;12(Suppl 2):43-54. [117 references]

Guideline Status

This is the current release of the guideline.

Regulatory Alert

FDA Warning/Regulatory Alert

Note from the National Guideline Clearinghouse: This guideline references a drug(s) for which important revised regulatory and/or warning information has been released.

- May 12, 2016 – Fluoroquinolone Antibacterial Drugs : The U.S. Food and Drug Administration (FDA) is advising that the serious side effects associated with fluoroquinolone antibacterial drugs generally outweigh the benefits for patients with sinusitis, bronchitis, and uncomplicated urinary tract infections who have other treatment options. For patients with these conditions, fluoroquinolones should be reserved for those who do not have alternative treatment options.

Recommendations

Major Recommendations

Level of evidence (I–IV) ratings are defined at the end of the "Major Recommendations" field.

Oesophagitis

- Oesophagitis should be treated empirically with fluconazole and oesophagoscopy should be performed if symptoms fail to settle initially (Ib).

- Specific treatment for oesophagitis in cases that fail to settle with empirical therapy should be directed at the cause identified by biopsy, culture and antimicrobial sensitivity testing (III).
- Azole-sensitive strains should be treated with fluconazole 50–100 mg by mouth (po) for 7–14 days (Ib), which is the preferred azole due to experience and superior bioavailability in comparison to itraconazole (Barbaro et al., 1996).
- Alternatives include caspofungin, 70 mg loading dose then 50 mg once a day intravenous (iv) (Villanueva et al., 2002), or liposomal amphotericin B 3 mg/kg once a day iv (Arathoon et al., 2002; Dieterich & Wilcox, 1996), used for the same duration as fluconazole. Of these, the side-effect profile of caspofungin and its efficacy in clinical trials make it the preferred agent when azole therapy cannot be used (III).
- Intermittent self treatment with fluconazole may be appropriate for individuals with persistently low CD4 cell counts and less frequent relapses and is likely to be the most appropriate strategy for most individuals with a history of relapsing oropharyngeal candidiasis in the highly active antiretroviral therapy (HAART) era where secondary prophylaxis should be reserved for select cases (Wilcox et al., 1996; Pagani et al., 2002) (IV).
- Cytomegalovirus (CMV) oesophagitis is treated with ganciclovir 5 mg/kg 2 times a day (bd) iv for 2–4 weeks, or until symptoms/signs have resolved (Wilcox, Schwartz, & Clark, 1995; Wilcox, Straub, & Schwartz, 1995) (III).
- Valganciclovir may be substituted for iv ganciclovir at 900 mg bd orally for some or all of the duration if symptoms are not severe enough to interfere with oral absorption on the basis of studies showing efficacy for CMV disease in transplant patients (Singh et al., 2008) but there is a paucity of data in human immunodeficiency virus (HIV)-related CMV disease of the gastrointestinal tract (IV). Secondary CMV prophylaxis for oesophageal disease is not routinely indicated, unless there is concomitant ophthalmological disease.
- Herpes simplex oesophagitis is treated with aciclovir 5–10 mg/kg 3 times a day (tid) iv, followed by 400 mg 5 times a day orally for a total of 14 days (Wilcox & Monkemuller, 1997) (III) or oral valaciclovir 1 g bd orally.
- After presentation with infectious oesophagitis, early initiation of HAART should be considered (Zolopa et al., 2009) (IV).

Diarrhoea

- Every effort should be made to confirm a specific diagnosis in patients with significant immunosuppression (IV).

Acute Diarrhoea Due to Bacteria and Viruses

Presentation

- Stool and blood cultures should be included in the routine diagnostic work-up of diarrhoea in HIV (IV).
- In the United Kingdom (UK), *Clostridium difficile* toxin assessment and/or culture should be carried out in all HIV-seropositive individuals presenting with acute diarrhoea (IV).

Treatment

- If a bacterial cause is suspected from the history, antimicrobial therapy may be indicated. Principles of therapy are as for HIV-seronegative individuals and acute bacterial diarrhoea in individuals with preserved CD4 counts (>200 cells/μL) does not usually require treatment (IV). In general, when individuals present with acute bacterial diarrhoea and a CD4 count <200 cells/μL, therapy will be indicated (IV). When indicated, the choice should be guided by *in vitro* sensitivity patterns and antimicrobial susceptibility testing should be requested if not routine. Whilst the majority of isolates will be sensitive to ciprofloxacin 500 mg bd po for 5 days there are increasing reports of resistance, in both *Campylobacter* species (spp) and *Salmonella* spp. In addition, the relationships between fluoroquinolones and *C. difficile* infection and methicillin-resistant *Staphylococcus aureus* (MRSA) colonization are resulting in less empirical use of this agent. Treatment should therefore be reserved for confirmed cases, as guided by sensitivity testing. In exceptional cases where the patient presents with signs of sepsis or severe symptoms the benefits of empirical treatment may outweigh the potential risks (IV).
- First episodes of *C. difficile* infection should be treated with metronidazole with consideration of vancomycin for fulminant disease, relapsing disease or non-responsive infection (IV), following the recommendations for treatment in HIV-seronegative populations outlined in Department of Health guidelines (Department of Health and Health Protection Agency, 2009). Therapy is indicated for *C. difficile* infection regardless of the CD4 cell count.
- Acute bacterial diarrhoea in HIV-seropositive individuals with CD4 counts >200 cells/μL usually does not require treatment, but should be treated when the CD4 count is <200 cells/μL (IV).
- Acute bacterial diarrhoea should be treated as per susceptibility tests and local guidance (IV).

Impact of HAART

- The incidence of bacterial diarrhoea declined steadily after the introduction of HAART (Sanchez et al., 2005), therefore HAART is the mainstay of preventing bacterial diarrhoea (III).

Cytomegalovirus

Treatment

- First-line treatment for CMV colitis is iv ganciclovir (5 mg/kg twice daily) for 14–28 days (Ib).
- Immediate optimization of HAART should be considered (IV).
- Therapeutic drug monitoring may be required to ensure adequate HAART absorption (IV).

Cryptosporidium spp

Treatment

- First-line treatment for cryptosporidiosis is with effective antiretroviral therapy (III).
- Nitazoxanide is effective in adults and children who are not severely immunosuppressed (IIb).

Microsporidiosis

Treatment

- *Enterocytozoon bieneusi* may respond to oral fumagillin (20 mg tid for 14 days) (Molina et al., 2000), but with significant haematological toxicity (Dieterich et al., 1994). This agent is not currently widely available. Nitazoxanide, albendazole and itraconazole have also been studied. Of these agents, albendazole (400 mg bd for 21 days) is recommended for initial therapy, particularly for *Encephalitozoon intestinalis* (Dieterich et al., 1994; Molina et al., 1998) (III).

Other Parasites and Helminths Causing Diarrhoea (Usually Chronic)

Giardiasis

- Giardiasis is treated with metronidazole 400 mg tid po for 7 days or 1 g daily for 3 days, or tinidazole 500 mg bd po for 7 days or 2 g once only po (Gardner & Hill, 2001) (III); see Table 4.3 in the original guideline document.

Cyclospora cayetanensis

- The clinical and parasitological response to standard doses of trimethoprim-sulphamethoxazole (TMP-SMX) (960 mg twice daily) is rapid and 7 days is usually sufficient. Ciprofloxacin 500 mg bd is an alternative but response is slower and incomplete (Verdier et al., 2000) (IIb).

Isospora belli

- It is implicated in 10% to 20% of cases of chronic HIV-related diarrhoea in the tropics and is an occasional cause of biliary disease. Treatment traditionally has been with TMP-SMX 960 mg 4 times a day (qid) po for 10 days though 960 mg bd appears also to be effective (Verdier et al., 2000; Pape, Verdier, & Johnson, 1989) (III) and secondary prophylaxis with the same antibiotic (960 mg 3 times a week) is essential as relapse is common and there is indirect (Sorvillo et al., 1995) and direct evidence for efficacy (Verdier et al., 2000; Pape, Verdier, & Johnson, 1989).

Strongyloides stercoralis

- Uncomplicated infection is treated with ivermectin 200 µg/kg once a day po for 1 or 2 days, which is more effective than the alternative treatment of albendazole 400 mg bd po for 3 days (Zaha et al., 2004; Johnston et al., 2005; Suputtamongkol et al., 2008) (III).

Definitions:

Level of Evidence

Ia	Evidence obtained from meta-analysis of randomized controlled trials
Ib	Evidence obtained from at least one randomized controlled trial
IIa	Evidence obtained from at least one well designed controlled study without randomization
IIb	Evidence obtained from at least one other type of well designed quasi-experimental study
III	Evidence obtained from well designed non-experimental descriptive studies

IV	Evidence obtained from expert committee reports or opinions and/or clinical experience of respected authorities

Clinical Algorithm(s)

None provided

Scope

Disease/Condition(s)

- Gastrointestinal opportunistic infections
  - Oesophagitis
  - Acute diarrhoea due to bacteria and viruses
  - Cytomegalovirus (CMV) colitis
  - Cryptosporidiosis
  - Microsporidiosis
  - Giardiasis
  - *Cyclospora cayetanensis*-related diarrhoea
  - *Isospora belli*-related diarrhoea
  - *Strongyloides stercoralis*-related diarrhoea
- Human immunodeficiency virus (HIV) seropositivity

Guideline Category

Diagnosis

Management

Prevention

Treatment

Clinical Specialty

Family Practice

Gastroenterology

Infectious Diseases

Internal Medicine

Pathology

Preventive Medicine

Radiology

Intended Users

Advanced Practice Nurses

Physician Assistants

Physicians

Guideline Objective(s)

To help physicians in the United Kingdom investigate and manage human immunodeficiency virus (HIV)-seropositive patients suspected of or having a gastrointestinal opportunistic infection

Target Population

Human immunodeficiency virus (HIV)-seropositive patients suspected of or having a gastrointestinal opportunistic infection

Interventions and Practices Considered

Diagnosis

1. Oesophagitis
    - Oesophagoscopy after failure of empirical treatment
    - Biopsy
    - Culture
    - Antimicrobial sensitivity testing
2. Diarrhoea
    - Stool and blood cultures
    - *Clostridium difficile* toxin assessment and/or culture

Treatment

1. Oesophagitis
    - Empirical fluconazole
    - Specific treatment for oesophagitis directed at the cause: fluconazole, caspofungin, liposomal amphotericin B, ganciclovir, valganciclovir, aciclovir, valaciclovir
    - Early initiation of highly active antiretroviral therapy (HAART)
2. Diarrhoea
    - Antimicrobial therapy guided by in vitro sensitivity patterns and antimicrobial susceptibility testing
    - Metronidazole for *C. difficile* infection
    - Vancomycin for fulminant, relapsing, or non-responsive *C. difficile* infection
    - HAART optimization and therapeutic drug monitoring
    - Ganciclovir for cytomegalovirus (CMV) colitis
    - Nitazoxanide for cryptosporidiosis
    - Fumagillin, nitazoxanide, albendazole, or itraconazole for microsporidiosis
    - Metronidazole or tinidazole for giardiasis
    - Trimethoprim-sulfamethoxazole (TMP-SMX) or ciprofloxacin for *Cyclospora cayetanensis* infection
    - TMP-SMX for *Isospora belli* infection
    - Ivermectin or albendazole for *Strongyloides stercoralis* infection

Major Outcomes Considered

- Sensitivity and specificity of diagnostic tests
- Incidence of diarrhoea
- Relapse rate
- Response rate
- Development of drug resistance
- Morbidity and mortality
- Resolution of infection

- Adverse events related to therapy
- Quality of life

Methodology

Methods Used to Collect/Select the Evidence

Searches of Electronic Databases

Description of Methods Used to Collect/Select the Evidence

The PubMed database was searched under the following headings: HIV or AIDS and diarrhoea, oesophagitis, candida, *Clostridium difficile*, cryptosporidium, cyclospora, cytomegalovirus, entamoeba, giardia, herpes, isospora, microsporidia, mycobacteria, parasites, salmonella, shigella, strongyloides.

All information considered had to have been published in a peer review journal or presented at an international human immunodeficiency virus (HIV) meeting in abstract form. Inclusion/exclusion criteria essentially required that the information was relevant to the diagnosis, treatment or prevention of the specified opportunistic infection in HIV-positive individuals. Information of relevance to other related immunocompromised groups was also taken into consideration if the section authors felt relevant. Case reports were included and the review was not restricted only to clinical trials or meta-analyses. Search dates were from 1980 to January 2011.

Number of Source Documents

Not stated

Methods Used to Assess the Quality and Strength of the Evidence

Weighting According to a Rating Scheme (Scheme Given)

Rating Scheme for the Strength of the Evidence

Level of Evidence

Ia	Evidence obtained from meta-analysis of randomized controlled trials
Ib	Evidence obtained from at least one randomized controlled trial
IIa	Evidence obtained from at least one well designed controlled study without randomization
IIb	Evidence obtained from at least one other type of well designed quasi-experimental study
III	Evidence obtained from well designed non-experimental descriptive studies
IV	Evidence obtained from expert committee reports or opinions and/or clinical experience of respected authorities

Methods Used to Analyze the Evidence

Review of Published Meta-Analyses

Systematic Review

Description of the Methods Used to Analyze the Evidence

Not stated

Methods Used to Formulate the Recommendations

Expert Consensus

Description of Methods Used to Formulate the Recommendations

Not stated

Rating Scheme for the Strength of the Recommendations

Not applicable

Cost Analysis

A formal cost analysis was not performed and published cost analyses were not reviewed.

Method of Guideline Validation

Not stated

Description of Method of Guideline Validation

Not applicable

Evidence Supporting the Recommendations

References Supporting the Recommendations

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Type of Evidence Supporting the Recommendations

The type of supporting evidence is identified and graded for each recommendation (see the "Major Recommendations" field).

Benefits/Harms of Implementing the Guideline Recommendations

Potential Benefits

Accurate diagnosis and appropriate treatment of gastrointestinal opportunistic infections in human immunodeficiency virus (HIV)-seropositive individuals

Potential Harms

- Medication-related side effects and toxicity
- Refer to Appendix 1 in the original guideline document for side effects of certain drug formulations.

Contraindications

Contraindications

- Fluconazole should not be used in pregnancy.
- Refer to Appendix 1 in the original guideline document for contraindications of certain drug formulations.

Qualifying Statements

Qualifying Statements

- These guidelines are primarily intended to guide practice in the United Kingdom and related health systems. Although it is hoped they can provide some guidance in developed countries there are some important distinctions in this environment and individual recommendations may not be as applicable in this setting.
- In the appendices in the original guideline document there is an A–Z of drugs used in the management of opportunistic infections. This is intended as a guideline but readers are advised to follow the discussion of dosing and the evidence for specific treatments provided in the text. In some cases alternative treatments are provided in the appendix in the original guideline document. These are not discussed in the text and these are mainly of historical interest and readers should be aware that these are not, in general, supported by the evidence base for treatments discussed in the text. It should also be noted that as evidence of drug toxicity, interactions, pregnancy risk and cost is rapidly evolving the table should be considered in association with the updated summary of product characteristics (SPC) for the agent and other relevant sources of drug information.
- Recommendations based upon expert opinion have the least evidence but perhaps provide an important reason for writing the guidelines: to produce a consensual opinion about current practice. It must, however, be appreciated that such opinion is not always correct and alternative practices may be equally valid. The recommendations contained in these guidelines should therefore be viewed as guidelines in the true spirit of the term. They are not designed to be restrictive nor should they challenge research into current practice. Similarly, although the British HIV Association (BHIVA) Opportunistic Infection Guidelines Group seeks to provide guidelines to optimize treatment, such care needs to be individualized and the authors have not constructed a document that they would wish to see used as a 'standard' for litigation.
- The clinical care of patients with known or suspected opportunistic infections (OIs) requires a multidisciplinary approach, drawing on the skills and experience of all healthcare professional groups. Moreover, these guidelines emphasize that inpatients with human immunodeficiency virus (HIV)-related disease often need rapid access to a variety of diagnostic tests and radiological interventions that may not be immediately available at local hospitals. Furthermore, expert interpretation of these tests by supporting specialties such as radiology, histopathology, microbiology and virology is often required. Optimal care of opportunistic infection can only be achieved by the close cooperation of these healthcare professionals and unless all are intimately involved in the care of patients, it is likely that the outcome will be less favourable. In keeping with BHIVA standards for HIV clinical care, patients needing inpatient care for HIV-related disease should ordinarily be admitted to an HIV centre or the relevant tertiary service in liaison with the HIV centre.

Implementation of the Guideline

Description of Implementation Strategy

An implementation strategy was not provided.

Implementation Tools

Mobile Device Resources

For information about availability, see the *Availability of Companion Documents* and *Patient Resources* fields below.

Institute of Medicine (IOM) National Healthcare Quality Report Categories

IOM Care Need

Getting Better

Living with Illness

IOM Domain

Effectiveness

Identifying Information and Availability

Bibliographic Source(s)

Beeching NJ, Jones R, Gazzard B. Gastrointestinal opportunistic infections. In: British HIV Association and British Infection Association guidelines for the treatment of opportunistic infection in HIV-seropositive individuals 2011. HIV Med. 2011 Sep;12(Suppl 2):43-54. [117 references]

Adaptation

Not applicable: The guideline was not adapted from another source.

Date Released

2011 Sep

Guideline Developer(s)

British HIV Association - Disease Specific Society

British Infection Association - Professional Association

Source(s) of Funding

British HIV Association

Guideline Committee

BHIVA Guidelines Writing Group on Opportunistic Infection

Composition of Group That Authored the Guideline

Section Authors: NJ Beeching, Liverpool School of Tropical Medicine, UK; R Jones, Chelsea & Westminster Hospital, London, UK; B Gazzard, Chelsea & Westminster Hospital, London, UK

Group Joint Chair: Dr Mark Nelson, Chelsea & Westminster Hospital, London, UK

Group Joint Chair: Professor David Dockrell, University of Sheffield, UK

Group Joint Chair: Dr Simon Edwards, Mortimer Market Centre, London, UK

Writing Group Members: Dr Brian Angus, John Radcliffe Hospital, Oxford, UK; Dr Simon Barton, Chelsea & Westminster Hospital, London, UK; Dr Nick Beeching, Liverpool School of Tropical Medicine, UK; Prof Colm Bergin, St James's Hospital, Dublin, Ireland; Dr Marta Boffito, Chelsea & Westminster Hospital, London, UK; Dr Ronan Breen, Royal Free Hospital, London, UK; Dr Jonathan Cartledge, Mortimer Market Centre, London, UK; Dr Susan Clarke, St James's Hospital, Dublin, Ireland; Dr Martin Fisher, Brighton and Sussex University Hospital, Brighton, UK; Dr Andrew Freedman, Cardiff University School of Medicine, UK; Prof Brian Gazzard, Chelsea & Westminster Hospital, London, UK; Dr Alison Grant, London School of Hygiene and Tropical Medicine, UK; Dr Julia Greig, Royal Hallamshire Hospital, Sheffield, UK; Dr Rachael Jones, Chelsea & Westminster Hospital, London, UK; Prof Saye Khoo, University of Liverpool; Prof Clifford Leen, Edinburgh University, UK; Dr Marc Lipman, Royal Free Hospital, London, UK; Dr Hadi Manji, National Hospital for Neurology & Neurosurgery, London, UK; Prof Robert Miller, Mortimer Market Centre, London, UK; Miss Suzanne Mitchell, Chelsea and Westminster Hospital, London, UK; Dr Ed Ong,

Newcastle General Hospital, UK; Dr Anton Pozniak, Chelsea & Westminster Hospital, London, UK; Dr Matthias Schmid, Newcastle General Hospital, UK; Miss Marianne Shiew, Chelsea & Westminster Hospital, London, UK; Prof Mervyn Singer, University College London, UK; Dr Ed Wilkins, North Manchester General Hospital, UK; Dr Ian Williams, Royal Free and University College Medical School, London, UK; Dr Chris Wood, North Middlesex University Hospital, London, UK; Ms Rosy Weston, St Mary's Hospital, Imperial College, London, UK

Financial Disclosures/Conflicts of Interest

The British HIV Association (BHIVA) has a clear policy of declarations of interests within the Association:

- BHIVA requires that all members of guidelines writing groups, as well as any expert external peer reviewers, must declare all interests and membership of other committees retrospectively on an annual basis, to give protection to individuals working as members of writing groups.
- All members of guidelines writing groups must undertake a declaration of interests prior to serving on a writing group and this declaration is confirmed and repeated at the publication of each set of completed guidelines published.
- The details given in declaration forms are retained on a register at the Secretariat and can be made available for publication, if required.

Guideline Status

This is the current release of the guideline.

Guideline Availability

Electronic copies: Available from the British HIV Association (BHIVA) Web site . Also available as a smartphone app from the BHIVA Web site .

Availability of Companion Documents

None available

Patient Resources

None available

NGC Status

This NGC summary was completed by ECRI Institute on July 30, 2014. This summary was updated by ECRI Institute on May 18, 2016 following the U.S. Food and Drug Administration advisory on Fluoroquinolone Antibacterial Drugs.

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